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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,521	10/02/2003	Gary M. Silver	FC-1-C1-PUS-1	9982

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HESKA CORPORATION
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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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08/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/678,521

Applicant(s)

SILVER ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 62-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Applicant's filing of a terminal disclaimer in the paper of 6/5/2007, is acknowledged. Claims 62-65 are still at issue and are present for examination. Upon further consideration it has been determined that the previous rejection under 112 first paragraph should not have been withdrawn. Further applicants previous amendment of the claims on 10/2/2006, should have resulted in a rejection under 112 first paragraph under Written Description. Accordingly this action is made non-final. Any inconvenience to applicants is apologized for.

Terminal Disclaimer

The terminal disclaimer filed on 6/5/2007 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of expiration of U.S. Patent No. 6,291,222 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

Claim 63 is objected to because of the following informalities: Claim 63 recites "comprising a nucleic acid molecule as set forth in Claim 62". It is suggested that this be amended to "comprising the nucleic acid molecule as set forth in Claim 62".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 62-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acid molecule encoding a polypeptide having the amino acid sequence of SEQ ID NO: 54 wherein said polypeptide has carboxylesterase activity, does not reasonably provide enablement for any nucleic acid molecule comprising SEQ ID NO: 72. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is acknowledged that a similar rejection to that below was made in the office action of 7/3/2006, followed by applicants amendment of claims 62-65 in the response of 10/2/2006. The rejection was then withdrawn in the office action of 3/22/2007.

Upon further consideration the rejection is deemed appropriate on the following basis.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 60, 61 and 63-65 are so broad as to encompass any nucleic acid molecules comprising SEQ ID NO: 72, wherein the encoded protein has an undefined activity.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the function of the encoded proteins of the extremely large number of nucleic acids broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to those nucleic acid molecules encoding a protein with the full-length amino acid sequence of SEQ ID NO: 54, wherein said encoded protein has carboxylesterase activity.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any nucleic acid molecule which encodes a protein comprising SEQ ID NO: 72 because the specification does not establish: (A) regions of the protein structure which may be modified without effecting carboxylesterase activity; (B) the general tolerance of carboxylesterases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a carboxylesterase with an expectation of obtaining the desired

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biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the carboxylesterase activity claimed and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to arrive at the majority of those nucleic acids of the claimed genus having an undisclosed function/activity.

It is noted that SEQ ID NO: 72 is but a 216 internal amino acid fragment of the 570 amino acid sequence of the full-length sequence of SEQ ID NO: 54. This internal amino acid fragment does not have carboxylesterase activity.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make **and use** the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any nucleic acid molecule which encodes a protein comprising SEQ ID NO: 72, having an undisclosed function/activity. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of how to use those nucleic acids encompassed by the claims is unpredictable and the experimentation left to those skilled in the art is unnecessarily,

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and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 62-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

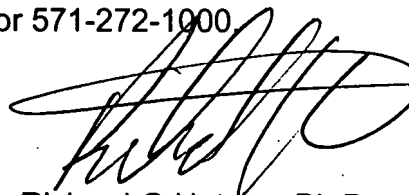
Claims 62-65 are directed to all possible nucleic acid molecules comprising SEQ ID NO: 72. The specification, however, provides the representative species of that nucleic acid encoding SEQ ID NO: 54, wherein the encoded polypeptide has carboxylesterase activity. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species that would help applicants describe the claimed genus. The specification also fails to describe additional representative species of these nucleic acids by any identifying structural characteristics or properties other than encoding a polypeptide comprising SEQ ID NO: 72, for which no predictability of function is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', is written over a horizontal line.

Richard G Hutson, Ph.D.
Primary Examiner
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